and delisting pursuant to paragraph (b)(1) of this section.

(4) *Non-applicability of certain procedures and requirements.* (i) A decision by the Secretary to accept a request by a PSO to relinquish voluntarily its status as a PSO pursuant to paragraph (c)(2) of this section does not constitute a determination of a deficiency in PSO compliance with the Patient Safety Act or with this Subpart.

(ii) The procedures and requirements of §3.108(a) of this subpart regarding deficiencies including the opportunity to correct deficiencies and to be heard in writing, and the procedures and requirements of §3.108(b) are not applicable to determinations of the Secretary made pursuant to this subsection.

(d) *Public notice of delisting regarding removal from listing.* If the Secretary removes an entity from the list of PSOs following revocation of acceptance of the entity's certification pursuant to §3.108(b)(1), voluntary relinquishment pursuant to §3.108(c)(3), or expiration of an entity's period of listing pursuant to §3.104(e)(1), the Secretary will promptly publish in the FEDERAL REGISTER and on the AHRQ PSO website, or in a comparable future form of public notice, a notice of the actions taken and the effective dates.

(e) *Expedited revocation and delisting*—(1) *Basis for expedited revocation.* Notwithstanding any other provision of this section, the Secretary may use the expedited revocation process described in paragraph (e)(3) of this section if he determines—

(i) The PSO is not in compliance with this part because it is or is about to become an entity described in §3.102(a)(2).

(ii) The parent organization of the PSO is an entity described in §3.102(a)(2) and requires or induces health care providers to report patient safety work product to its component PSO; or

(iii) The circumstances for revocation in paragraph (a)(1) of this section exist, and the Secretary has determined that there would be serious adverse consequences if the PSO were to remain listed.

(2) Applicable provisions. If the Secretary uses the expedited revocation process described in paragraph (e)(3) of this section, the procedures in paragraphs (a)(2) through (5) of this section shall not apply and paragraph (a)(1) and paragraphs (b) and (d) of this section shall apply.

(3) *Expedited revocation process.* (i) The Secretary must send the PSO a written notice of deficiency that:

(A) Identifies the evidence that the circumstances for revocation and delisting under paragraph (a)(1) of this section exist, and any corrective action that the PSO must take if the Secretary determines that corrective action may resolve the matter so that the entity would not be delisted; and

(B) Provides an opportunity for the PSO to respond in writing to correct the facts or the legal bases for delisting found in the notice, and to offer any other grounds for its not being delisted.

(ii) The notice of deficiency will be presumed to be received five days after it is sent, absent evidence of the actual receipt date.

(iii) If the PSO does not submit a written response to the Secretary within 14 calendar days of actual or constructive receipt of such notice, whichever is longer, the Secretary may revoke his acceptance of the PSO's certifications and remove the entity from the list of PSOs.

(iv) If the PSO responds in writing within the required 14-day time period, the Secretary may take any of the following actions:

(A) Withdraw the notice of deficiency;

(B) Provide the PSO with more time to resolve the matter to the Secretary's satisfaction; or

(C) Revoke his acceptance of the PSO's certifications and remove the entity from the list of PSOs.

§3.110 Assessment of PSO compliance.

The Secretary may request information or conduct announced or unannounced reviews of, or site visits to, PSOs, to assess or verify PSO compliance with the requirements of this subpart and for these purposes will be allowed to inspect the physical or virtual sites maintained or controlled by the PSO. The Secretary will be allowed to inspect and/or be given or sent copies of any PSO records deemed necessary

and requested by the Secretary to implement the provisions of this subpart. Such PSO records may include patient safety work product in accordance with § 3.206(d) of this part.

§ 3.112 Submissions and forms.

(a) Forms referred to in this subpart may be obtained on the PSO Web site (*http://www.pso.ahrq.gov*) maintained for the Secretary by AHRQ or a successor agency or on successor publication technology or by requesting them in writing by e-mail at *pso@ahrq.hhs.gov*, or by mail from the Agency for Healthcare Research and Quality, CQuIPS, PSO Liaison, 540 Gaither Road, Rockville, MD 20850. A form (including any required attachments) must be submitted in accordance with the accompanying instructions.

(b) Information submitted to AHRQ in writing, but not required to be on or attached to a form, and requests for information from AHRQ, may be submitted by mail or other delivery to the Agency for Healthcare Research and Quality, CQuIPS, PSO Liaison, 540 Gaither Road, Rockville, MD 20850, by facsimile at (301) 427–1341, or by e-mail at *pso@ahrq.hhs.gov*.

(c) If a submission to the Secretary is incomplete or additional information is needed to allow a determination to be made under this subpart, the submitter will be notified if any additional information is required.

Subpart C—Confidentiality and Privilege Protections of Patient Safety Work Product

§ 3.204 Privilege of patient safety work product.

(a) *Privilege*. Notwithstanding any other provision of Federal, State, local, or Tribal law and subject to paragraph (b) of this section and § 3.208 of this subpart, patient safety work product shall be privileged and shall not be:

(1) Subject to a Federal, State, local, or Tribal civil, criminal, or administrative subpoena or order, including in a Federal, State, local, or Tribal civil or administrative disciplinary proceeding against a provider;

(2) Subject to discovery in connection with a Federal, State, local, or Tribal civil, criminal, or administrative proceeding, including in a Federal, State, local, or Tribal civil or administrative disciplinary proceeding against a provider;

(3) Subject to disclosure pursuant to section 552 of Title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, local, or Tribal law;

(4) Admitted as evidence in any Federal, State, local, or Tribal governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or

(5) Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

(b) *Exceptions to privilege*. Privilege shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(1) Disclosure of relevant patient safety work product for use in a criminal proceeding, subject to the conditions at § 3.206(b)(1) of this subpart.

(2) Disclosure to the extent required to permit equitable relief subject to the conditions at § 3.206(b)(2) of this subpart.

(3) Disclosure pursuant to provider authorizations subject to the conditions at § 3.206(b)(3) of this subpart.

(4) Disclosure of non-identifiable patient safety work product subject to the conditions at § 3.206(b)(5) of this subpart.

(c) *Implementation and enforcement by the Secretary*. Privilege shall not apply to (and shall not be construed to prohibit) disclosures of relevant patient safety work product to or by the Secretary if such patient safety work product is needed to investigate or determine compliance, or to seek or impose civil money penalties, with respect to this part or the HIPAA Privacy Rule, or to make or support decisions with respect to listing of a PSO.

§ 3.206 Confidentiality of patient safety work product.

(a) *Confidentiality*. Subject to paragraphs (b) through (e) of this section,